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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/603,794

06/25/2003

Syed F.A. Hossainy

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11/24/2008

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EXAMINER

SELLMAN, CACHET I

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

11/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,794	<b>Applicant(s)</b> HOSSAINY ET AL.	
	<b>Examiner</b> CACHET I. SELLMAN	<b>Art Unit</b> 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-29 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-29 and 32-35 is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 08/07/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/856,984 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 has the limitation that the stand deviation of the mean release rate of the active agent in a 24 hour period is lower than the standard deviation of the mean release rate for a group of devices which have not been exposed to the temperature. The specification enables one to expose the polymer coating to a temperature which is above the glass transition temperature in order to decrease the variance of release rates for a group of stents. However, the specification does not provide support for exposing the coated stents to any temperature above ambient temperature in order to

decrease the variance of release rates for a group of stents. The temperature is dependent upon the polymer used within the coating.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-7, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6153252).

Hossainy et al. discloses a process for applying a coating to a stent. The process comprises applying a composition having a polymer and a solvent (see col. 4, line 1 – col. 6, line 67); allowing the solvent to evaporate (see Example 1). The polymer applied in Example 1 is a copolymer of 45:55 e-caprolactone and glycolide which has a glass transition temperature of -8 C and a melting point temperature of 65°C as evidence, see US patent 5,468,253 (examples 3-5) which was determined using DSC. The composition after being applied to the stent is air dried for 12 hours followed by heating in a 60°C vacuum oven for 24 hours.

Hossainy et al. does not explicitly teach that a dry coating having less than about 2% residual fluid content is heated to a temperature greater than ambient temperature for a duration of time. However, Hossainy et al. does teach heating the composition on the stent until it is completely dry therefore it would have been obvious that at some

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point in the drying period the coating reached a point where it comprised less than 2 % residual fluid and was continually heated until it was completely dry having no residual fluid therefore the limitations of **claims 10, 11** are met. In regards to the limitation that the standard deviation of the mean release of the active agent in a 24 hour period is lower than the standard deviation of the mean release of a group of devices which have not been exposed to the temperature. According to the specification, devices which have been exposed to a temperature greater than the glass transition temperature of the polymer used in the coating would result in the standard deviation of the mean release rate of the active agent to be lower than that of a group of devices which were not exposed to such temperature. Therefore, the devices of Hossainy et al. would inherently have a lower standard deviation of mean release rates (see paragraph 0042 of Published Application).

As shown in example 1, a primer layer is applied to the stent followed by a reservoir layer having the active agent as required by **claim 2**. Hossiany et al. teaches a top coat can be applied to prevent release of the active agent (see col. 7, line 18-20) as required by **claim 3**. The device is a stent as required by **claim 4**. The active agent does not degrade when exposed to the temperature as required by **claim 6**. The drying is a rapid process so as to not diffuse the drug into the coating (see col. 9, lines 18-20) as required by **claim 7**. The active agent can be rapamycin (see col. 8, line 31) as required by **claim 12**.

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6. Claims 2, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 645137).

Hossiany et al. teaches a process for applying a composition having a therapeutic substance, a fluid and a polymer to a prosthesis and removing the fluid (see abstract, col. 5, line 49). The polymer can be bioabsorbable polymers such as poly-D, L-lactic acid, polycaprolactone, etc or biostable polymers such as polyethylene vinyl acetate, ethylene vinyl alcohol copolymers (see col. 5, line 49 - col. 6, line 13 and Examples). The fluid/solvent is removed by exposing to heat at 60 - 65°C under vacuum conditions.

Hossainy et al. does not explicitly teach that a dry coating having less than about 2% residual fluid content is heated to a temperature greater than ambient temperature for a duration of time. However, Hossainy et al. does teach heating the composition on the stent until it is completely dry therefore it would have been obvious that at some point in the drying period the coating reached a point where it comprised less than 2 % residual fluid and was continually heated until it was completely dry having no residual fluid therefore the limitations of **claims 10 and 11** are met. The polymer can be ethylene vinyl acetate copolymer which when heated to 60-65°C is greater than the glass transition temperature. In regards to the limitation that the standard deviation of the mean release of the active agent in a 24 hour period is lower than the standard deviation of the mean release of a group of devices which have not been exposed to the temperature. According to the specification, devices which have been exposed to a temperature greater than the glass transition temperature of the polymer used in the

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coating would result in the standard deviation of the mean release rate of the active agent to be lower than that of a group of devices which were not exposed to such temperature. Therefore, the devices of Hossainy et al. would inherently have a lower standard deviation of mean release rates (see paragraph 0042 of Published Application).

The polymer can be ethylene vinyl alcohol copolymer, ethylene vinyl acetate copolymer as required by **claims 8**.

***Allowable Subject Matter***

7. Claims 13-29 and 32-35 are allowed.
8. The following is a statement of reasons for the indication of allowable subject matter: The prior art discloses applying a composition to a stent where the composition includes a polymer and solvent, removing the solvent from the coating and exposing the coating to a temperature which is greater than the glass transition temperature of the polymer. However, the prior art fails to state that the polymer is semicrystalline and has a percent crystallinity of 40 - 75 %.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman  
Examiner  
Art Unit 1792

/C. I. S./  
Examiner, Art Unit 1792

/William Phillip Fletcher III/  
Primary Examiner, Art Unit 1792